NO. 80644-6 (w/ erratums)

SUPREME COURT OF
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

Respondent.

SUPPLEMENTAL BRIEF OF PETITIONER (CORRECTED)

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CERTIFICATE OF SERVICE
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October 6, 2008

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ORIGINAL

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THE COURT OF APPEALS IMPROPERLY CREATED NEW FACTS, FINDINGS AND POST HOC RATIONALIZATIONS

The role of the Court of Appeals in reviewing an Order entered by an administrative body is to determine if the agency's findings are supported by substantial evidence, and, if they are, to determine whether those findings provide sufficient support for the agency's conclusions of law. *E.g.,* Inland Foundry Co., Inc. v. Department of Labor and Industries, 106 Wash.App. 333, 340-342, 24 P.3d 424, 428-429 (Div. 3,2001) There is no authority, and DOH has never claimed authority, for the Court of Appeals in conducting that review to disregard the findings that the agency made and to replace them with findings that it itself has made.

In addition, it is one of the "fundamental principles of administrative law" – repeatedly restated and reaffirmed by federal and state courts – that, precisely because of the expertise and role of administrative bodies as agencies of a different branch of government,

> "'an agency's action must be upheld, if at all, on the basis articulated by the agency itself.' " [citing authority]

Gifford Pinchot Task Force v. U.S. Fish and Wildlife Service, 378 F.3d 1059, 1072 n. 9 (9TH Cir. 2004). *"Post hoc* rationalizations" will not be accepted. *Ibid. Accord: Drew v. Psychiatric Security Review Board,* 322 Or. 491, 500, 909 P.2d 1211, 1215 (1996).[1] *See also Pinto v. Massanari,*

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[1] (agencies must state the reasoning supporting their conclusions and even where facts are found which could support their conclusions on other, unstated reasoning, that will be insufficient if the actual reasoning . . . is not supportable).

249 F.3d 840, 847-848 (9th Cir. 2001):

> Although we can affirm the judgment of a district court on any ground supported by the record, *Downs v. Hoyt,* 232 F.3d 1031, 1036 (9th Cir.2000), we ***cannot*** affirm the decision of an agency on a ground that the agency did not invoke in making its decision [citing authority].

And the explanation must be "sufficient to enable us to conclude that the [agency's action] was the product of reasoned decisionmaking." *Motor Vehicle Mfrs. Assn. v. State Farm*, 463 U.S. 29, 52 (1983). Washington codified this law in 1988 when it enacted RCW 34.05.461(3). *See* Anderson, "The 1988 Washington Administrative Procedure Act – An Introduction," 64 Wash.L.Rev. 781, 782 (1989) (emphasizing importance of the APA requirement "that agencies explain carefully the rationale for their actions to "increas[e] agency accountability," "improv[e] the process of judicial review," and generally enable "executive, legislative and judicial review of agency action")

Prior to 1988, agency orders had only been required to state findings and conclusions, not supporting reasons, nor the evidence on which they based findings framed in the words, or a paraphrase, of the governing statute. But under the new APA, per Professor Anderson:

> Initial and final orders should be responsive, articulate and complete. The new act requires . . . findings and conclusions and the reasons therefore on ***all*** [itals in original] material issues of law, fact or discretion . . . Findings which simply repeat the

> relevant statutory formulas must be accompanied by a description of the record evidence in support of the findings. [*Id* at 813]

In this case, instead of reviewing the findings and reasons actually made and given, the Court of Appeals manufactured facts and findings wholesale and created a theory to justify the Commission's decision that is nowhere to be found in the Order under appeal. The Court itself sought and adopted the "*post hoc* rationalizations" that were its judicial duty to reject. It is extraordinary that not only does it state as fact matters that the record – and especially the actual findings – shows clearly not to be true – but it does so even though Petitioner expressly warned it of these misstatements (which largely come from the DOH Respondent's Brief) and specifically cited the relevant record.

The Court is referred to Petitioner's Motion for Reconsideration for a discussion of some of the most obvious misstatements that appear in the Court of Appeals opinion. They are not repeated to avoid subjecting the Court to a re-reading of material it has already carefully reviewed. We rely on this Court to do whatever is necessary to prevent further injustice in this outrageous case.

We, therefore, confine ourselves here primarily to the rationale the Court of Appeals adopted to justify the Commission's decision. The Court did not review the record to see if it supported the agency findings;

it created its own findings and then asserted that they were supported by substantial evidence, without citation or other demonstration, without actual evidence in the record or in contradiction of the actual findings.

It is claimed that there were findings that Petitioner "created an unreasonable risk of harm to Patient One by using LISTEN to diagnose and treat allergies without any evidence the device was effective for that purpose" and "by using it without understanding how it worked." Opinion, pp. 11-12. Similarly, the Court says, again without citation, that the decision "was not based on Dr. Ames's diagnosis that Patient One had an egg allergy [*contra*: Findings, para 1.29]," but on "using . . . . a device he did not understand and for which he had no training" "to treat his egg allergy," Opinion, p.12. The Court holds that the device was inefficacious, because "[t]here was no evidence [it] was capable of curing allergies."

The assertions that Petitioner did not "understand" (whatever that means) the device and "that there was ***no*** evidence" that it was efficacious to treat allergies are not findings that the Commission made. These are the creation of the Court of Appeals, based on similar assertions in DOH's brief. But even DOH did not assert that there was "no evidence" that the device was efficacious. See its acknowledgment of evidence from Petitioner's colleagues, from the evidence of the two patients other than P1 who testified and from Dr. Ames' testimony of reports by hundreds of

patients of successes using NAET testing and therapy. RB 24-25, 37, 40.

To be sure, DOH challenges the reliability of the evidence, because it is "anecdotal" or empirical, not the result of formal studies. But it is nevertheless evidence, while there was no colorable evidence that the device was not efficacious. That is why the Court of Appeals established inefficacy by lawlessly shifting the burden of production on the issue to Petitioner, but even then Petitioner met that burden.[2]

The only basis that the MQAC order relies on for its finding that the device is inefficacious is its spurious finding that P1 did not have an egg allergy. As noted elsewhere, P1 did not claim that he had had no egg allergy. He merely stated that he did not have a reaction to eggs of the sort that *pro tem* PA, Ms. Paxton, described (hay fever symptoms) and that no one else had ever told him that he had egg allergy. CR 2269. Obviously, P1, who had many other allergic symptoms, was not competent to testify to whether his body suffered any adverse effects from eating eggs that only testing or professional medical diagnosis could determine. *See, e.g.*, *Edwards v. Bowen*, 672 F.Supp. 230 (E.D.N.C. 1987). And the fact that no one else had ever told him that he had any food allergies is meaningless in the absence of a contention, let alone evidence, that he had ever been

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[2] See OB 36, Reply Br. 16, CR 2970-2972, 2696-2700, 2730, 2732; CR 2164, 3037-3038, 3044-3048, 3051, 3061-3063, 3116.

tested for food allergies.

But the initial point to be emphasized is that the Commission did not ***find*** that there was no evidence of efficacy. This is a finding of fact that the Court of Appeals made, but with absolutely no authority to do so.

Similarly, the Commission did not find that Petitioner did not "understand" the device and the Court of Appeals had no authority to make that finding either. To be sure, there are findings that Petitioner "does not know the physics behind the LISTEN device, nor did he know the voltage or amperage" that it produces. But that does not mean he did not "understand" the device or how it works. The word "understand" here is fatally imprecise. In one sense, one could say that a person does not "truly" understand a device if he or she does not know the physics behind it. In that sense, many physicians, physician assistants and nurses who use computers, electric shavers, transistor radios, x-ray machines and other electronic devices do not understand them. On the other hand, if they know how to use them safely, know what they do, understand their purposes and effects, they have the necessary understanding. No doubt that is why the Commission did not find that Petitioner did not understand the device. There was ample evidence – some even reflected in the Findings – that in this sense he "understood" the device. For a sample of the evidence on Petitioner's extensive knowledge (which no one did or could deny) see

below.[3] The Findings themselves reflect how much of this knowledge was acquired over four years of using the device with fifty (50%) of his patients, from his mentor Dr. Nambudripad and the inventor of the device and, again as the Order finds, "from colleagues, from vendors and from attending conferences."[4]

Why did DOH assert the "*post hoc* rationalization" about Petitioner's lack of "understanding" and "evidence of efficacy" at the appellate level? It is because the reasons for the Commission's findings are insupportable. Neither the Commission's brief nor the Court of Appeals opinion attempts to defend them. Repeat: There is ***no*** attempt. The ultimate foundation of the entire decision is the insupportable finding that P1 did not have an egg allergy. It was on the basis of this finding that the device was held to be inefficacious, which in turn became an indispensable support for the findings of negligence and unreasonable risk of harm. CR 1861-1862. Without them the house of cards collapses.

What the panel did here was to diagnose P1's physical condition two and one half years after the fact with no testing or physical examination. If the one physician on the panel had done such a thing in

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3 See from DOH's exam of Petitioner CR 2090, 2094, 2102, 2103, 2104, 2105, 2106, 2148, 2154, 2159, 2161, 2164, 2176, 2177, 2178, 2179, 2180.

4 See CR 1856-1857, ¶¶1.8, 1.9, 1.10 (course attended by nurse "increased his understanding and knowledge about the device"), 1.11

her practice, relying solely on the patient's perceived "reactions," it would have been malpractice, itself a violation of the uniform disciplinary act. See *Ancier v. State, Dept. of Health.*[5]

Although the Court describes – erroneously in major part (P1 did not testify that "he had *no symptoms indicating* an allergy to eggs") – the sub-finding on which the Commission based its assertion that P1 did not have an egg allergy, it does not argue that this is substantial evidence or sufficient to support a conclusion of law under RCW 18.130.180(16) that the device was inefficacious. Its argument does not address Petitioner's attack on these subfindings, in essence assuming P1 ***did*** have an egg allergy. Op. p. 12.

The existence of these new findings is at once illegal and powerful evidence that the Commission's findings are so insupportable as to fall far below the level of the arbitrary and capricious. which a responsible reading of Petitioner's briefing in this appeal would have made clear.

THE COURT OF APPEALS ADOPTED A VERSION OF THE *JAFFE* RULE THAT GOES FAR BEYOND ANYTHING ADOPTED IN THIS STATE OR ELSEWHERE

The *Jaffe* rule[6] (which is stated in *Davidson* and *Brown*, *infra*) is

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5 140 Wash.App. 564, 571, 166 P.3d 829, 833 (Div. 1, 2007) (failure "to conduct physical exams that are crucial for arriving at correct diagnoses" and "to undertake baseline clinical testing for purposes of making a diagnosis or for eliminating other possible diagnoses or illnesses" properly found unprofessional conduct).

6 *Jaffe v. State Dept. of Health*, 135 Conn. 339, 64 A.2d 330 (1949).

essentially that expert evidence of the standard of care need not be introduced in a professional disciplinary proceeding. The MQAC panel and the Court of Appeals took the rule far beyond that. Most obviously, they applied it in the decision under RCW 18.130.180(16) (promotion of an inefficacious device, treatment, etc. for personal gain) which did not involve practice standards. They also applied it to scientific, medical and technical facts other than the standard of care but essential to the negligence findings.

It is at least understandable why courts have adopted *Jaffe* on the issue of the standard of care if by "the standard of care" one means what a prudent practitioner would do under the circumstances. See RCW 7.70.040. That is not really a standard at all, but an invitation to apply expert judgment to the peculiar facts of a particular case. In that situation, the ultimate decision may seem to be only a conclusion or inference based on experience from the facts in the record.

This is not true, however, of facts like the nature and symptoms of food allergies, the efficacy of a medical device, and the dangerousness of a drug, procedure or device. These are all facts that lay people cannot normally testify to. So, if they are to come in, they must come in by expert testimony. But the panel and the Court of Appeal ruled that no such testimony need be elicited, effectively ruling that these matters need not be

proved by evidence in the record.

Petitioner has argued in his Petition for Review and the response to the Amicus Curiae brief that *Jaffe* when critically scrutinized is a jurisprudential catastrophe, clearly mistaken factually and literally absurd as a matter of logic. But if it is possible to be worse than *Jaffe*, extending it to technical facts other than the "standard of care" has managed that feat.

The Court of Appeals decision also goes beyond existing law by allowing the Commission to dispense with expert testimony when the hearing panel does not consist of a majority of physicians. In this case, there was only one physician. Even Connecticut, which gave us *Jaffe* and still unaccountably follows it, expressly requires that a majority of the relevant board consist of experts from the profession if expert testimony is to be dispensed with. *Jutkowitz v. Department of Health Services*, 220 Conn. 86, 110, 596 A.2d 374, 387 (1991). The Court of Appeals asserted that a majority of "medical professionals" was sufficient and that the *pro tem* physician's assistant was such a professional. A review of the medical practice act shows that the commission members who are physicians assistants – who were placed on the Commission for cases involving PAs – have to meet no requirements other than licensure. See RCW 18.71.015. They need not have practiced. The physicians, on the other hand, must go through the many years of medical school, internship,

residency, and often fellowships in addition to having practiced for at least five years. The PA – especially the newly minted PA which the statute allows to sit on the Commission – simply cannot have the experience with the physician standard of care that a physician would have.

After reviewing the Petition for Review, the Amicus Brief and Petitioner's response, Petitioner fears that it would test the Court's patience if it offers more than the most minimal additional treatment of the defects of *Jaffe* and of the reasons why its holding should be held not to be the law of Washington.

Accordingly, Petitioner will offer only a few observations and rely upon the Court's review of the papers already filed. For a useful summary of the reasons why the majority of courts – and all of the leading courts considering it (*e.g.*, California, Illinois, Massachusetts, Texas, Minnesota, Oregon and Wisconsin) – have resoundingly rejected *Jaffe*, see *Martin v. Sizemore*, 78 S.W. 249, 271 (Tenn. Ct.App. 2001) and *Huff, infra.* For a recent holding that the *Jaffe* doctrine is unconstitutional, see *Balian v. Board of Licensure in Medicine*, 722 A.2d 364, 368-69 (Me.,1999).

Petitioner has suggested in other papers that *Johnston* apparently chose deliberately not to adopt the *Jaffe* rule, because it was cited and argued in the agency's briefing and this Court did not choose to cite it in support of its decision. That this was deliberate is suggested even more strongly by the

fact that *Jaffe* had been adopted by the Court of Appeals in *Johnston* and that *Davidson* was decided several months before *Johnston* and, of course, it, too adopted *Jaffe*. Petitioner suggests that this Court did not cite *Jaffe* in *Johnston* because it understood that it did not need its authority and was aware of its controversy. The determination of negligence in *Johnston* amounted to nothing more than an inference from expert evidence already on the record that would have made it clear to a layperson that the respondent had been grossly negligent. The Court's reliance on the authority of expert bodies to use their expert knowledge to test the reliability and to draw reasonable inferences from the evidence was exactly right on the facts of that case.

Today, under the APA as it was revised in 1988, the provision that supports the approach in *Johnston* is RCW 34.05.641(5):

> Where it bears on the issues presented, the agency's experience, technical competence, and ***specialized knowledge*** may be used in the evaluation of evidence.

Emphasis added. However, fundamental principles of statutory interpretation require that all of the provisions of a statute dealing with the same general subject matter must be reconciled and harmonized. *E.g.*, *In re Estate of Kerr*, 134 Wn.2d 328, 343, 949 P.2d 810, 817 (1998) There are at least three other relevant APA sections. Most obviously, RCW 34.05.461(4):

> Findings of fact shall be based exclusively on the evidence of record in the adjudicative proceeding and on matters officially noticed in that proceeding.

RCW 34.05.452(5) provides in part that

> Official notice may be taken of (a) any judicially cognizable facts, (b) ***technical or scientific facts within the agency's specialized knowledge***, and (c) codes or standards that have been adopted by an agency of the United States, of this state or of another state, or by a nationally recognized organ-nation or association.

Emphasis added. This section goes on to require notice and an opportunity to contest the matters proposed to be noticed. *Ibid.*

The provision requiring that facts "be based exclusively on the evidence of record" might appear to preclude the expert body from using its specialized knowledge *dehors* the record, unless using specialized knowledge to "evaluate evidence" is something different from not "bas[ing]'" "findings of fact . . . exclusively on the evidence of record." Even more obviously, the provision requiring an opportunity to contest "official notice of... technical or scientific facts within the agency's specialized knowledge" might seem to preclude a body's use of such knowledge in the evaluation of evidence unless there is notification of the knowledge to be used.

But it would surely be impossible to have a working administrative system if most of the types of facts the legislature must have had in mind in RCW 34.5.461(5) had to be disclosed in some way. This is even more true if RCW 34.05.461(4) were interpreted to require that every piece of knowledge used in evaluation must be subject to litigation on the record.

A part of the problem is addressed by one commentator:

> The difference between an administrative tribunal's use of non-record information included in its expert knowledge, as a substitute for evidence or [official] notice, and its application of its background in evaluating and drawing conclusions from the evidence that is in the record is primarily a difference of degree rather than of kind.

E. Gellhorn, "Rules of Evidence and Official Notice in Formal Administrative Proceedings," 1971 Duke L.J. 1, 43 (1971). It may be a matter of degree, but the term "background" seems useful to limit the knowledge that may be used without disclosure. That sounds like general knowledge and, in this context, knowledge that would be common to any competent member of the profession or, perhaps, member of a specialty of the profession. What people think they know from experience, however, can be found to be wrong when its disclosure ultimately occurs.

Accordingly, two additional limitations on the undisclosed use of information seem required. "Official notice may not be taken of a fact that is not obvious and notorious either to the average person or to an expert in the given field." Schwartz, Administrative Law, sec. 7.18, p. 412 (3d ed. 1991). If that is true of official notice, it should be even more true of information used privately to evaluate evidence – *i.e.*, it "must be obvious or notorious" to an expert in the field. This would seem to mean that if the fact is being controverted in good faith in the case, evidence directly relevant to

establishing it must be introduced on the record and litigated. The point is covered by the second limitation that Professor Schwartz reports: When "the facts involved were what have been termed the disputed adjudicative facts at the center of the controversy," "[t]hey can only be established by evidence at the hearing." *Id* at 413.

Since the standard of care ordinarily involves a critical, disputed fact – what is or are the actual accepted practice(s) of members of the profession in the litigated situation and/or the facts of the profession or discipline from which a necessary inference of prudence or imprudence should be made – in most situations, and therefore the general rule should be that, there must be expert evidence of the standard and of the conduct allegedly violating it.

In cases like *Davidson*[7] (chiropractor massaged genitals and breasts of patients with a vibrator), *Johnston*, *Brown* and *Clausing v. State*, 90 Wn.App. 863, 955 P.2d 394 (Div. 1,1998) where the reasonable prudence required is so clear that it arguably could be decided by a non-expert body, an expert need not formally and expressly state the standard. And this is recognized by the majority rule. *See, e.g., Huff v. North Dakota State Board*, 690 N.W. 2d 221, 228 (N.D. 2004).

NOTICE: THE COURT OF APPEALS IGNORED THE REQUIREMENTS

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7 *See Davidson v. Dept. of Licensing*, 33 Wn.App. 783, 657 P.2d 810 (1983); *Johnston v. Medical Board*, 99 Wn.2d 466, 663 P.2d 457 (1983); *Brown v. Dental Board*, 94 Wn. App. 7, 972 P.2d 101 (Div. 3, 1998)

THAT THE STATEMENT OF CHARGES CLEARLY PLEAD THE "FACTUAL BASIS" AND THAT CHARGES BE"CLEAR AND SPECIFIC"

Petitioner emphatically argued in its opening and reply briefs that DOH had failed to meet the requirement of WAC 246-11-250(b) that the "the factual basis" of the case be set forth in the statement of charges, because more than half of the facts found to establish liability were not set forth in that document (as they could not have been, because they were not part of the DOH case until days into the hearing).

Despite this, the Court of Appeals completely ignored the DOH regulation and never ruled that the "factual basis" had been stated. The Court also ignored this Court's due process requirement of "clear and specific charges," and never ruled that the charges against Petitioner were in fact "clear and specific." Instead, the Court merely asserted that Petitioner had been given "adequate notice" – is 'adequate" notice sufficient in a quasi-criminal case with all that is at stake – by pleadings that did not exist and by two statements of charges which clearly did not state what the Court said they stated. We will not repeat the many arguments made by Petitioner on these matters in his Motion for Reconsideration. We pray that the Court will carefully read the argument set forth there, as well as in Petitioner's Reply Brief – two documents which are very important in this case, because of the

many new arguments DOH made for the first time in its Respondent's Brief.[8]

Two matters relating to the notice issue, however, merit further attention. The first is that DOH's preliminary and amended preliminary hearing statements stated in terms that there would be no material facts other than those in the amended statement of charges and that it had no intention of amending. CR 965-966; App. 1. What that meant, Petitioner contends, is that the theory of liability being prosecuted was a very simple one, based on the claims in the statement of charges that the device had not been cleared by the FDA or that if it had been cleared, it had not been cleared for the use Petitioner made of it. On that asserted predicate – flimsy as Petitioner knew it to be under federal food and drug law – DOH's entire theory of liability rested, because that was the only culpability pleaded in the statement of charges. Thus, moral turpitude, negligence, and inefficacy were all based on the assertion of an FDA violation – *e.g.*, using a device in violation of the FDA was negligence and immoral as well as a violation of RCW 18.130.180(7) and a device not cleared by the FDA was *ipso facto* inefficacious. If the Court reviews the DOH opening statement, which is attached to this brief, it will confirm that this is in fact what DOH was relying

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8 Hopefully, the Court will recognize that DOH by urging new "post hoc rationalizations" of the Commission decision, instead of defending the Commission's Order as it was written and reasoned, deprived Petitioner of the right to address in its Opening Brief, with its greater page allowance, what turned out to be the major issues in the appeal.

on. See CR 2053-2069: App. 2. It will then see why Petitioner prepared the limited case it did, why he was not prepared for the change of theory that occurred during and after the hearing and why many factual matters that might have enlightened this Court if the initial DOH case had required Petitioner to mount a more elaborate defense never appeared on the record.[9]

The second matter relating to notice that deserves attention, especially because the Court of Appeals ignored it, is Petitioner's contention that he had not been given notice that the assertions later included in Paragraph 1.27 of the Findings were in issue (Respondent failed to adequately investigate the safety of the LISTEN device). CR 1862. Petitioner has attacked the ***evidentiary*** basis of this finding, OB 38-42, but the Court of Appeals opinion shows no awareness of it. Here, however, the issue is notice and the absence of an allegation of failure to adequately investigate from the charges.

The Presiding Officer actually ruled on this issue. He excluded the theory on Day 3 of the hearing when DOH in responding to Petitioner's motion to dismiss first attempted, based on the testimony elicited by Ms. Paxton, to assert a failure to investigate the device's safety.

> MR. ARMSTRONG: The Department's position on what he didn't do is he failed to investigate this machine. He

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9 *E.g.*, about why old line regulators devote public resources to pursue harmless alternative modalities that attract patients despite the absence of insurance coverage or advertising of any kind and about how little "scientific evidence" supports the practices of conventional practitioners while they decry the absence of rigorous formal studies for alternative care.

failed to investigate from the manufacturer, he failed to investigate from the FDA, and they already admitted that they talk to doctors all the time.

MR. BISHIN: I object. It's not in the Statement of Charges. There was no evidence that he failed to investigate, only that he said, that he indicated generally what he did in the way of investigation.

JUDGE DEBUSSCHERE: ***Objection sustained.***

CR 2677 (emphasis added) The theory was excluded by the Presiding Officer and the related finding should not have appeared in the Order. Perhaps ¶1.27 was meant merely as an admonition, thus explaining why the conduct alleged was not found to be negligent or to create unreasonable risk.

CONCLUSION

This case should be remanded to the Commission with directions to dismiss, to return Petitioner whole to the *status quo ante* the imposition of the penalties imposed on him below and to provide relief under RCW 4.84.350 and any other appropriate authority.

Respectfully submitted this 6th day of October 2008.

LAW OFFICES OF
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By _____
William R. Bishin WSBA No. 8386

Attorneys for Geoffrey S. Ames, M.D.

SUPREME COURT OF
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

Respondent.

SUPPLEMENTAL BRIEF OF PETITIONER

APPENDIX

1. **DOH PRE-HEARING STATEMENT**

2. **DOH HEARING OPENING STATEMENT**

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL CARE QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice Medical License of: GEOFFREY S. AMES, M.D., License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DEPARTMENT'S *AMENDED* PREHEARING STATEMENT

COMES NOW the State of Washington, Department of Health, Dental Quality Assurance Commission (Department), by and through its attorneys, CHRISTINE O. GREGOIRE, Attorney General, and KEITH D. ARMSTRONG, Assistant Attorney General, and provides the following Amended Prehearing Conference Statement.

I. AMENDMENTS TO PLEADINGS

The Department does not anticipate any amendments to the pleadings at this time.

II. UNRESOLVED DISCOVERY

The Department has no unresolved discovery.

III. STATEMENT OF FACTS

The Department incorporates by reference the factual allegations set forth in the Statement of Charges Section 1.

IV. STATEMENT OF ISSUES

The following ultimate issues are to be decided at hearing:

1. Did the Respondent engage in unprofessional conduct as alleged under RCW 18.130.180(1), (4), (7), (16); RCW69.04.040(1) and (3); 21U.S.C. § 331(c)?

2. If unprofessional conduct is proven by the Department, what is the appropriate sanction under RCW 18.130.160?

V. WITNESSES

The Department intends to call **Respondent** as an adverse witness.

The Department may also call all or some of the following witnesses, in any order, in person or by telephone:

1. Patient One, Complainant.
2. Neil Ogden, Director, Center for Devices and Radiologic Health and General Surgery, Federal Drug Administration (301) 594-1307.
3. Rich Sherman, PhD., Research Physiologist, Chief Consultant for Research, Orthopedic Surgery, Madigan Army Medical Center, Tacoma.
4. Department of Health Investigator, Joseph Grangnelli, BSN, RN, Investigation/Legal Unit.

The Department reserves the right to call in its case in chief any witness identified by Respondent. The Department reserves the right to call rebuttal witnesses who may or may not be identified in its witness list. The Department further reserves the right to amend its witness list for good cause shown.

VI. RELIEF REQUESTED

The Department requests affirmance of the violations alleged in the Statement of Charges and the imposition of appropriate sanctions.

VII. EXHIBITS

The Department may submit all or some of the following exhibits:

1. Documents provided by Patient One:
   a. July 31, 2001 Memo from Patient One to MQAC recounting his experience with Respondent, INV.00246-47.
   b. July 12 & 16, 2001 email correspondence between Patient One and Sharon Seidel, DHS-EHIB, regarding Seidel's JAMA article on hair analysis for lead, minerals, INV.00258-59.
2. Patient One's Medical Records, INV.00299-348.

JUDGE DeBUSSCHERE: That was the first exhibit. I imagine it's --

MS. PAXTON: The letter to the FDA?

JUDGE DeBUSSCHERE: No, it's a letter that I removed, so the first exhibit of the Respondent's packet, yes, a letter to FDA dated 8/18/92, that was removed and will be provided, provided that the proper foundation is made.

The parties will be referring to their exhibits during the hearing, so the Commission members have that copy so that they can refer to those exhibits during testimony. Also each Panel members has a copy of the Respondent's hearing brief. With that it's now an opportunity for opening statement. Go ahead, Mr. Armstrong, you're first.

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OPENING STATEMENT

BY MR. ARMSTRONG:

Thank you. Good morning Panel and Judge DeBusschere. I'm going to start my opening statement talking about doctors, since that's the subject of our disciplinary hearing.

Doctors are a lifeline to everybody in this room, and they're respected, with high character and moral standards. Because of that we believe what

they say. We listen to them. We rely on their judgment and their expertise, and why not, their lives are on our hands.

My name is Keith Armstrong. I'm an assistant attorney general representing the Department in this case. I'm going to be presenting the case, and Respondent here is Doctor Geoffrey Ames, about his professional practice as a doctor east of the mountains.

Today's evidence is going to focus on a practice that's below the standard of care for Washington. It's a practice that the Department received a complaint, investigated and determined that it was unprofessional conduct, and we're bringing the evidence to you to determine if that is truly the case.

We have a Statement of Charges that has details about one patient and a device. That device stands right there to my left and to your right. That is the LISTEN device, and I'll talk more about that later. The evidence that we intend to show for these few days is that Doctor Ames abused his position as a physician. We're going to show evidence that he performed techniques and used that electronic device to practice medicine. The

Department is alleging, there are charges that this device is not a proper use of his medical expertise, is not a proper device to be used in medical practice. We're going to present four witnesses to prove our case. The first I'm going to have Doctor Ames himself come and talk about his care with Patient 1 and his practice. Next I will have, who's in route now from Pasco, is Patient 1. He should be here at any time now. He is a certified industrial hygienist who works for the federal government over in the Hanford area. He will be talking about his care provided by Doctor Ames.

Next we're going to have, in this order we're going to have Doctor Richard Sherman. He's a research physiologist. He is the chief consultant for research for orthopedic surgery at Madigan Army Medical Center.

Last we're going to have Neil Ogden. He's the branch chief of the general surgery devices branch and radiological general surgery at the Food and Drug Administration. He is the branch chief of that. His division evaluates this type of machine to determine if it's a proper machine to be marketed, cleared for whatever purposes, so we're going to have his testimony by phone. The rest of them will be

here in person.

Those four individuals, counting the Respondent, will be the total of the Department's case. The evidence that we have in document form, we have Doctor Ames' statement as a response to the investigation, and we have the patient's records, so we have his medical records here for you all to review, and I'll be making some reference to that.

Other than that, that will be the total sum that you will see from the Department as far as Doctor Ames' practice with Patient 1, but also we'll be talking in general about his practice of medicine. That will be the subject.

This case is going to talk about his practice with this machine, principally. That's what it's going to deal with.

My opposition is attorney Mr. Bishin. They're going to present testimony to rebut our case, that using this machine in the practice of medicine is below the standard of care, and you're going to have topics and evidence from all kinds of experts on all types of topics, none dealing with allergy treatment.

MR. BISHIN: With what?

MR. ARMSTRONG: Allergy treatment.

This case is going to be principally, one principal issue is whether Doctor Ames' treatment of allergy with Patient 1 was legitimate, efficacious or inefficacious, or whether it was below the standard of care or at the standard of care.

The defense is going to rebut the Department's case by claiming that the machine is registered by the FDA and all they're doing is off-label use. The Department's witnesses will debunk that idea, that the device is not registered by the FDA. The Department's evidence is going to show it is not approved by the FDA and it's not cleared by the FDA, not only to not treat allergies, but the evidence is going to show it is not cleared to treat anything.

My opposition's rebuttal is going to try to talk about a lot of other subjects other than allergy treatment by a physician. I ask you not to listen to that evidence. Once you hear from --

MR. BISHIN: I object to that, Your Honor.

JUDGE DeBUSSCHERE: I'll sustain the objection. It is argumentative.

MR. ARMSTRONG: Let me say it this way: None of the evidence that my opposition will bring

will overcome what the FDA has to say, and that's the only person who can make the determination whether this machine is authorized or not. They may try to divert your attention with other type of methodologies of treatment. I ask you to focus on the issue of treatment of allergies for Patient 1. The Department is going to show evidence that Doctor Ames used his medical license to entice patients into unorthodox, unproven, unauthorized and inefficacious treatments without the informed consent or knowledge of the risk of these treatments.

The Department is going to show evidence that his care for these patients was not at the standard of care for professional doctors, but below that.

The credibility of the witnesses is going to be very critical. Patient 1's credibility is going to be very critical in this case. Doctor Ames' credibility is going to be very critical, but what I want you to focus on is after you have heard those two individuals, I would like you to focus on what the FDA has to say, because they're going to have the ultimate conclusion on what the device can do and what it cannot do. So if it doesn't come from the FDA, I don't think they will have anything to

say, once this case is over. That's the story of this case, Doctor Ames treating Patient 1 for allergies, whether that was appropriate or not, and his types of treatment.

I ask the Commission to listen to their evidence and listen to our evidence, and at the end of the day their evidence is not going to hold water to what Patient 1 and the FDA has to say. Thank you for your attention this morning.

JUDGE DeBUSSCHERE: Mr. Bishin, your opening statement?

MR. BISHIN: Yes, Your Honor. Thank you.

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OPENING STATEMENT

BY MR. BISHIN:

My name is William Bishin. I represent Doctor Geoffrey Ames in connection with this matter that you're going to be hearing and deciding. This case is, in an important sense, a case about Doctor Ames' use of this particular device. In fact it certainly is the way the Statement of Charges reads. You'll see that almost all of it is about this particular device, and a large part of the Statement of Charges refers to and tries to paraphrase portions